201-14662

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Ms. Marianne L. Horinko
US Environmental Protection Agency
1200 Pennsylvania Ave., N. W.
Washington, DC 20460

Re: Revision of 2-Butene-1,4-diol (110-64-5) Documents
Via Electronic Submission to: Oppt.ncic@epa.gov

Registered with EPA as:
BPPB Consortium, **Registration Number**

Dear Acting Administrator Horinko;

On behalf of the BPPB Consortium, Toxicology and Regulatory Affairs is hereby responding to the U.S. EPA's comments posted June 17, 2003 on the Chem-RTK HPV Challenge Web site for the Test Plan and Robust Summaries of 2-Butene-1,4-diol (110-64-5). The U.S. EPA's comments can be broadly grouped into two categories; testing related comments and comments pertaining to information in the Test Plan or Robust Summaries. The following are responses to the U.S. EPA's comments/questions based on these two groups:

Testing Related Issues

U.S. EPA Comment (1): EPA disagrees that the submitted data are adequate for the biodegradation endpoint.

BPPB Response (1): We agree that the ready biodegradation study as presented in the original robust summaries was not up to the preferred standard; however, information was available in that study to validate the ready biodegradability of 2-Butene-1,4-diol. Two other materials of known biodegradability (one readily biodegradable and the other inherently biodegradable) were studied with the same protocol and gave the expected results. Hence, the study had both positive and negative control compounds, which establish validity of the result. Information about the two other compounds has been added to the robust summary for the closed bottle test. In addition to strengthening the closed-bottle test result, we believe that the weight of evidence coming from the closed-bottle test, the Zahn-Wellens test and structural analogs and considerations is sufficient to establish the biodegradability of 2-Butene-1,4-diol for the purposes of the HPV program.

U.S. EPA Comment (2): The submitter needs to conduct a 96-hr LC50 acute toxicity study for fish.

BPPB Response (2): Although we believe that the duration of the present study was sufficient to establish the toxicity of this highly water-soluble material to fish, we acknowledge that the available study does not meet all the guidelines for reliability. An OECD Guideline 203 study is now recommended in the test plan and will be conducted.

Test Plan and Robust Summaries

U.S. EPA Comment (3): A number of the submitted robust summaries for acute mammalian toxicity provided limited details.

BPPB Response (3): The acute mammalian toxicity studies were reviewed and what additional information was available was added to the robust summaries. These are older studies that were conducted by scientifically defensible methods and are considered of adequate quality even if many of the methodological details were not incorporated in the final reports.

The Test Plan and robust summaries have been revised to incorporate the changes noted above. The BPPB Consortium will initiate testing in accordance with the Revised Test Plan, and final robust summaries will be prepared and submitted to the U.S. EPA that cover the results of this revised testing. Please contact me at (618) 539-5280 if you have any questions or comments.

Sincerely,

Elmer Rauckman, PhD, DABT
Consulting Toxicologist

Attachments:

Testing Plan	110-64-5-Rev Test Plan.pdf
Robust Summaries	110-64-5-Rev RS.pdf